

HEALTHPOINT

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KAY MARY HARRELL
MANAGER, REGULATORY AFFAIRS

August 26, 1999

Dockets Management Branch (FHA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Docket No. 99D-0529

Gentlemen:

Healthpoint, Ltd. (HP) submits these comments to the docket on the Draft Guidance for Industry on Changes to an Approved ANDA and NDA. HP is a distributor of generic and innovator topical drug products.

In general, HP lauds the efforts of the FDA in producing a draft guidance to not only provide detailed interpretation of the new 21 CFR 314.70, but also to clearly provide regulatory relief in many categories of change. It is noted that, especially in the packaging section, many new changes will be permitted as CBE-30 supplements and annual report updates for the topical liquid and semisolid dosage forms.

HP, would like to take the opportunity to suggest that the list of examples in section IX.D.6, lines 707-709 be expanded to include the following:

- ◆ Deletion of a tube crimp sealant
- ◆ Change in composition of a tube crimp sealant

The justification for making these annual reportable changes is based in the knowledge that there is virtually no product contact with the crimp sealant material. The sealant itself is only applied to the very end of the tube at the open end. Using a standard industry double saddle fold technique will provide for 5-7 folds to close the filled tube. Accordingly, there is virtually no way the product can migrate to the region where the sealant is applied. Therefore, since the potential for product contact with the sealant material is minimal to non-existent, DPT believes this is an appropriate addition to the list of examples in the aforementioned section.

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We appreciate the opportunity to provide comments to this draft guidance, and look forward to its issuance on November 21, 1999.

Very truly yours,

A handwritten signature in cursive script, appearing to read "Kay Mary Harrell".

Kay Mary Harrell
Manager, Regulatory Affairs

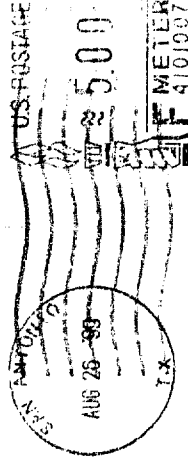
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